PROPOSED RULE MAKING

CR-102 (June 2004)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

Agency: Washington State Board of Health

☒ **Preproposal Statement of Inquiry was filed as WSR** 05-06-030 ; or
☐ **Expedited Rule Making--Proposed notice was filed as WSR** _____; or
☐ **Proposal is exempt under RCW 34.05.310(4).**

☒ **Original Notice**
☐ **Supplemental Notice to WSR** _____
☐ **Continuance of WSR** _____

Title of rule and other identifying information: (Describe Subject) Chapter 246-650 WAC Newborn Screening. Establishes rules to detect, in newborns, congenital disorders leading to developmental impairment or physical disabilities as required by RCW 70.83.050.

Hearing location(s):

Seattle Airport Hilton & Conference Center
17620 Pacific Highway South
Seattle, WA 98188-4001

Date: December 7, 2005 Time: 1:30 p.m.

Submit written comments to:
Name: Michael Glass
Address: 1610 NE 150th, Shoreline WA 98155
or mike.glass@doh.wa.gov
e-mail http//www3.doh.wa.gov/policyreview
fax (206)418-5415 by (date) November 28, 2005

Date of intended adoption: January 3, 2006
(Note: This is **NOT** the **effective** date)

Assistance for persons with disabilities: Contact
Juli Terao-Fast by November15, 2005
TTY (1) 800-833-6388 or (206) 418-5537

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose is to revise WAC 246-650-010, -020 and -030 Newborn Screening to add cystic fibrosis to the definitions (Section -010) and to the panel of required screening tests for all newborns (Section -020) and to provide a timeline for implementation of screening for cystic fibrosis (Section -030). Screening will be conducted by the department of health using the same dried blood spot specimen currently submitted by hospitals for screening for the nine conditions currently specified in WAC 246-650-020.

Reasons supporting proposal: Newborn screening for cystic fibrosis is recommended by several national groups, including the Centers for Disease Control and Prevention, American College of Medical Genetics, the National March of Dimes and the American Academy of Pediatrics. The Washington State Board of Health and Department of Health have convened two advisory committees to consider the evidence and make recommendations. The first committee consisted of experts in public health and cystic fibrosis who were convened to review the medical/technical evidence. The group found that cystic fibrosis met the technical requirements of the Board's Criteria for Adding Disorders to the Newborn Screening Program. Subsequently, a broadly representative group of stakeholders was convened to consider all of the evidence. After reviewing the evidence and issues, this committee has recommended that cystic fibrosis be added to the disorders for which all infants born in our state must be screened.

Statutory authority for adoption: RCW 70.83.050

Statute being implemented: RCW 70.83.020

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

DATE 11/2/05

NAME (type or print)
Craig McLaughlin

SIGNATURE

TITLE
Executive Director

CODE REVISER USE ONLY

CODE REVISER'S OFFICE
STATE OF WASHINGTON
FILED

NOV 2 2005

TIME 11:29 AM PM

WSR 05-22-126

(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:
None

Name of proponent: (person or organization) Washington State Board of Health, and Department of Health

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting.....	Michael Glass	1610 NE 150th ,Shoreline WA 98155	(206-)
Implementation....	same	same	(same)
Enforcement.....	same	same	(same)

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

☐ Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:
Name:
Address:

phone ( ) _____
fax ( )_____
e-mail _____

☒ No. Explain why no statement was prepared.
The proposed rule does not impose any costs on small businesses. And therefore a small business economic impact statement is not required under RCW 19.85.030

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes A preliminary cost-benefit analysis may be obtained by contacting:
Name: Ala Mofidi
Address:

PO Box 47890
Olympia, WA 98504-7890

phone (360) 236-4055
fax (360)586-7424
e-mail ala.mofidi@doh.wa.gov

☐ No: Please explain:

AMENDATORY SECTION (Amending WSR 03-24-026, filed 11/24/03, effective 12/25/03)

WAC 246-650-010 Definitions. For the purposes of this chapter:

(1) "Board" means the Washington state board of health.

(2) "Biotinidase deficiency" means a deficiency of an enzyme (biotinidase) that facilitates the body's recycling of biotin. The result is biotin deficiency, which if undetected and untreated, may result in severe neurological damage or death.

(3) "Congenital adrenal hyperplasia" means a severe disorder of adrenal steroid metabolism which may result in death of an infant during the neonatal period if undetected and untreated.

(4) "Congenital hypothyroidism" means a disorder of thyroid function during the neonatal period causing impaired mental functioning if undetected and untreated.

(5) "Cystic fibrosis" means a life-shortening disease caused by mutations in the gene encoding the cystic fibrosis transmembrane conductance regulator (CFTR), a transmembrane protein involved in ion transport. Affected individuals suffer from chronic, progressive pulmonary disease and nutritional deficits. Early detection and enrollment in a comprehensive care system provides improved outcomes and avoids the significant nutritional and growth deficits that are evident when diagnosed later.

(6) "Department" means the Washington state department of health.

((~~(6)~~)) (7) "Galactosemia" means a deficiency of enzymes that help the body convert the simple sugar galactose into glucose resulting in a buildup of galactose and galactose-1-PO_4 in the blood. If undetected and untreated, accumulated galactose-1-PO_4 may cause significant tissue and organ damage often leading to sepsis and death.

((~~(7)~~)) (8) "Hemoglobinopathy" means a hereditary blood disorder caused by genetic alteration of hemoglobin which results in characteristic clinical and laboratory abnormalities and which leads to developmental impairment or physical disabilities.

(9) "Homocystinuria" means deficiency of enzymes necessary to break down or recycle the amino acid homocysteine resulting in a buildup of methionine and homocysteine. If undetected and untreated may cause thromboembolism, mental and physical

disabilities.

((~~(8)~~)) (10) "Maple syrup urine disease" (MSUD) means deficiency of enzymes necessary to breakdown the branch chained amino acids leucine, isoleucine, and valine resulting in a buildup of these and metabolic intermediates in the blood. If undetected and untreated may result in mental and physical retardation or death.

((~~(9)~~)) (11) "Medium chain acyl-coA dehydrogenase deficiency" (MCADD) means deficiency of an enzyme (medium chain acyl-coA dehydrogenase) necessary to breakdown medium chain length fatty acids. If undetected and untreated, fasting, infection or stress may trigger acute hypoglycemia leading to physical and neurological damage or death.

((~~(10)~~)) (12) "Newborn" means an infant born in a hospital in the state of Washington prior to discharge from the hospital of birth or transfer.

((~~(11)~~)) (13) "Newborn screening specimen/information form" means the information form provided by the department including the filter paper portion and associated dried blood spots. A specimen/information form containing patient information is "Health care information" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(6).

((~~(12) "Phenylketonuria" (PKU) means a deficiency of an enzyme necessary to convert the amino acid phenylalanine into tyrosine resulting in a buildup of phenylalanine in the blood. If undetected and untreated may cause severely impaired mental functioning.~~

~~(13) "Hemoglobinopathy" means a hereditary blood disorder caused by genetic alteration of hemoglobin which results in characteristic clinical and laboratory abnormalities and which leads to developmental impairment or physical disabilities.~~))

(14) "Phenylketonuria" (PKU) means a deficiency of an enzyme necessary to convert the amino acid phenylalanine into tyrosine resulting in a buildup of phenylalanine in the blood. If undetected and untreated may cause severely impaired mental functioning.

(15) "Significant screening test result" means a laboratory test result indicating a suspicion of abnormality and requiring further diagnostic evaluation of the involved infant for the specific disorder.

AMENDATORY SECTION (Amending WSR 03-24-026, filed 11/24/03, effective 12/25/03)

WAC 246-650-020 Performance of screening tests. (1) Hospitals providing birth and delivery services or neonatal care to infants shall:

(a) Inform parents or responsible parties, by providing a departmental information pamphlet or by other means, of:

(i) The purpose of screening newborns for congenital disorders,

(ii) Disorders of concern as listed in WAC 246-650-020(2),

(iii) The requirement for newborn screening, and

(iv) The legal right of parents or responsible parties to refuse testing because of religious tenets or practices as specified in RCW 70.83.020, and

(v) The specimen storage, retention and access requirements specified in WAC 246-650-050.

(b) Obtain a blood specimen for laboratory testing as specified by the department from each newborn prior to discharge from the hospital or, if not yet discharged, no later than five days of age.

(c) Use department-approved newborn screening specimen/information forms and directions for obtaining specimens.

(d) Enter all identifying and related information required on the specimen/information form following directions of the department.

(e) In the event a parent or responsible party refuses to allow newborn screening, obtain signatures from parents or responsible parties on the department specimen/information form.

(f) Forward the specimen/information form with dried blood spots or signed refusal to the Washington state public health laboratory no later than the day after collection or refusal signature.

(2) Upon receipt of specimens, the department shall:

(a) Perform appropriate screening tests for:

(i) ((~~Phenylketonuria~~)) Biotinidase deficiency, congenital hypothyroidism, congenital adrenal hyperplasia, ((~~and hemoglobinopathies,~~)) galactosemia, homocystinuria, hemoglobinopathies, maple syrup urine disease, medium chain acyl-coA dehydrogenase deficiency, and phenylketonuria;

(ii) ((~~Biotinidase deficiency, galactosemia, homocystinuria, maple syrup urine disease and medium chain acyl-coA dehydrogenase deficiency~~)) Cystic fibrosis according to the

schedule in WAC 246-650-030;

(b) Report significant screening test results to the infant's attending physician or family if an attending physician cannot be identified; and

(c) Offer diagnostic and treatment resources of the department to physicians attending infants with presumptive positive screening tests within limits determined by the department.

AMENDATORY SECTION (Amending WSR 03-24-026, filed 11/24/03, effective 12/25/03)

WAC 246-650-030 Implementation of screening to detect ((~~biotinidase deficiency, galactosemia, homocystinuria, maple syrup urine disease and medium chain acyl-coA dehydrogenase deficiency~~)) cystic fibrosis. The department shall implement screening ((~~tests for biotinidase deficiency, galactosemia, homocystinuria, maple syrup urine disease and medium chain acyl-coA dehydrogenase deficiency beginning in January 2004. Screening for these disorders shall be fully implemented~~)) to detect cystic fibrosis as quickly as feasible and not later than June ((~~2004~~)) 2006.